Exhibit 437

Report 19: Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

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Report 19: Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

May 12, 2022 • by War Room/DailyClout Pfizer Documents Analysis Project Team 5

Team Five: Review of Polack with comments and questions.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

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NEJM 383:27 12/31/2020.

Abstract:

BNT162b2: full length spike protein, nucleoside modified

21,720 BNT162b2 21728 Placebo

Severe covid after first dose:

- 9 in Placebo group
- 1 in BNT162b2

Cases of covid onset after at least 7 days after second dose:

- 8 cases in BNT162b2
- 162 cases in Placebo:

“The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of adverse events was low and was similar in the vaccine and placebo groups.” P2603 p3.

Main Body of Paper:

“A two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years or older. Safety over a median of 2 months was similar to that of other viral vaccines. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728),” P2603 p4.

“Safe and effective prophylactic vaccines are urgently needed to contain the pandemic, which has had devastating medical, economic, and social consequences.” P2604 p 1.

“Findings from studies conducted in the United States and Germany among healthy men and women showed that two 30 mg doses of BNT162b2 elicited high SARS-CoV-2 neutralizing antibody titers and robust antigen-specific CD8+ and Th1-type CD4+ cell responses.”

“Here we report safety and efficacy findings from the phase 2/3 part of a global phase 1/2/3 trial evaluating the safety, immunogenicity, and efficacy of 30 mg of BNT162b2 in preventing Covid-19 in persons 16 years of age or older.” P2604 p3.

“Collection of phase data on vaccine immunogenicity of phase 2/3 data on vaccine immunogenicity and the durability of the immune response to immunization is ongoing, and those data are not reported here.” P 2604 p 3.

Study group included HIV, hep B or C patients.

Exclusion: Prior history of covid-19, immunosuppression. P. 2604 p 5.

Pfizer conducted trial, collected the data, performed the data analysis, data interpretation, and the writing of the manuscript. “This data set and these trial results are the basis for an application for emergency use authorization. 9 (https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=featured_coronavirus)
” P2604 p 3.

Study Design:

Table S1, Online Supplementary Appendix: Explanation of the various denominator values for use in assessing the results (available NEJM.org)

- 44,820 subjects screened & 43,448 participants injected:

- BNT162b2

- 18,860 dose 1: 28 withdrew after adverse reaction.
- 18,556 dose 1 & 2: 48 discontinued after second
- 18,508 dose 1 & 2: completed 2-month follow-up

- Placebo

- 18,846 dose 1: 18 withdrew after adverse reaction.
- 18,530 dose 1 & dose 2: 95 discontinued after 2nd
- 18,435 dose 1 & dose 2 completed 2-month follow-up.

- 43,355 subjects Modified intention-to-treat (mITT) efficacy population.

- All age groups 12 years of age or older.
- 100 participants who were 12 to 15 years of age "...contributed to person time years but included no cases." P2605 p5.

- 40,137 subjects evaluated 7 days after the second dose "with or without evidence of prior infection".

- 37,706 subjects "Safety population" (defined by the FDA):

- Persons 16 years of age or older.
- Median of 2 months of follow-up as of October 9, 2020.

- 36,523 subjects evaluated for efficacy 7 days after the second dose and “who had no evidence of prior infection”.

- 8183 subjects = Reactogenicity Subset

Methods:

“Participants received two injections, 21 days apart, of either BNT162b2 or placebo, delivered in the deltoid muscle.” P2604 p6. Aspiration not mentioned.

Adults 16 years of age or older who were:

- Healthy or had
- Stable chronic medical conditions, including but not limited to
  - Human immunodeficiency virus (HIV),
  - Hepatitis B virus, or
  - Hepatitis C virus infection

Division of work:

- Pfizer:

1. Design and conduct of the trial,
2. Data collection,
3. Data analysis and interpretation
4. Writing of the manuscript.

- BioNTech:

- Trial sponsor
- Manufactured BNT162b2

- Contributed: interpretation of the data and the writing of the manuscript.

- **All the trial data were available to all the authors, who vouch for its accuracy and completeness and for adherence of the trial to the protocol, which is available with the full text of this article at NEJM.org. This data was not on the web site 4/13/2022.**

- An independent data and safety monitoring board reviewed efficacy and unblinded safety data.

Safety:

- Observation for 30 minutes after injection.

- Solicited data:

1. End points.
2. Specific local or systemic adverse events.
3. Use of antipyretic or pain medication within 7 days after the receipt of each dose of vaccine or placebo, as prompted by and recorded in an electronic diary in a subset of participants (the reactogenicity subset)

- Unsolicited: Unsolicited serious adverse events through 6 months after the second dose.

- Adverse event data through approximately 14 weeks after the second dose are included.

- Safety data are reported for all participants who provided informed consent and received at least one dose of vaccine or placebo.

- Per protocol, safety results for participants infected with HIV (196 patients) will be analyzed separately and are not included here.

- A stopping rule for the theoretical concern of vaccine-enhanced disease was to be triggered if the one-sided probability of observing the same or a more unfavorable adverse severe case split (a split with a greater proportion of severe cases in vaccine recipients) was 5% or less, given the same true incidence for vaccine and placebo recipients. Alert criteria were to be triggered if this probability was less than 11%.

Efficacy:

Efficacy of BNT162b2 against **confirmed Covid-19**:

- First Primary End Point: Onset of confirmed Covid-19 at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose. P. 2604

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Restated: Confirmed Covid-19 after 28 days following the initial dose. Covid-19 positives prior to 28 days were considered unvaccinated. P2605 p 3.

- Confirmed Covid Diagnosis: FDA criteria. (No reference provided).

- **One** of the following Symptoms:
  - Fever
  - Chills
  - Diarrhea
  - Vomiting
  - Loss of Taste
  - Loss of smell
  - New or increased:
    - Cough
    - SOB
    - Muscle pain

- Plus: a respiratory specimen in suspected SC2 + by NAAT obtained during symptomatic period +/- four days before.

- Second Primary End Point: was “efficacy in participants with and without evidence of prior infection.”P2605 p 3.

- Major secondary end points: Efficacy against severe covid. “Details are provided in the protocol.” P2605 p4.

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- Confirmed covid.

- One of the following:
  - Respiratory failure.
  - Acute neurologic event.
  - Renal dysfunction.
  - Hepatic dysfunction.
  - ICU Admission.

Results:

Reactogenicity: n = 8183.

Local:

- Younger recipients reported symptoms more often than older >55

Local Pain	< 55	>= 55
First Dose	83%	71%
Second Dose	78%	66%

.

- **Systemic:** More reports after second dose than first:

- Fatigue: 59% <55, 51% => 55, placebo 23%
- Headache: 51% < 55, 39% = >55, placebo 24%
- Temperature > 38 Deg C after second dose:
  - 16% < 55, 11% => 55
  - 9-40 deg C: 0.2% after 1st dose, 0.8% after 2nd dose; 0.1% placebo 1st and 2nd.
  - > 40 deg C: 2 subjects one in injected and placebo.
- Antipyretic/analgesic:
  - < 55: dose 1 = 28% & dose 2 = 45%.
  - => 55: dose 1 = 20% & dose 2 = 38%.
  - Placebo: dose 1 = 10 % & dose 2 = 14%.

Adverse Events: Table S3 (available online):

n= 43,252 according to published article. P2608 p 3.

n = 43,252 according to online Table S1 P 7. "Vaccinated N=43,448 minus 196 HIV+."

n = 43,252 according to online Table S3 P 9. "All enrolled." At least 1 dose.

Any Event, Any Event Related and Any Event Severe are statistically significant, Appendix 1.

	BNT162b2	Placebo	
n =	21621	21631	
All events	5770	2638	
Related	4484	1095	
% AE React	69%	31%	
% All AE Total	27%	12%	
% Rel. AE Total	21%	5%	

Rel = Related AE; P = Placebo

	BNT162b2	Placebo
Lymphadenopathy	64	6

Efficacy:

	BNT162b2	**Placebo**	**VE***
n =	18198	18325	
Surveillance Time	2.214	2.222	
Covid-19: >= 28 days after dose 2	**8**	80	
Covid-19: <28 days after dose 2+ Placebo	39	82	52%
All	47	162	
Study comparison	8	162	95%

*VE = Vaccine Efficacy

Discussion:

“A two-dose regimen of BNT162b2 (30 μg per dose, given 21 days apart) was found to be safe

and 95% effective against Covid-19.”

"The vaccine met both primary efficacy end points, with more than a 99.99% probability of a true vaccine efficacy greater than 30%."

"These results met our prespecified success criteria, which were to establish a probability above 98.6% of true vaccine efficacy being greater than 30%, and greatly exceeded the minimum FDA criteria for authorization.9"

"...in the interval between the first and second doses, the observed vaccine efficacy against Covid-19 was 52%, and in the first 7 days after dose 2, it was 91%, reaching full efficacy against disease with onset at least 7 days after dose 2."

"Of the 10 cases of severe Covid-19 that were observed after the first dose, only 1 occurred in the vaccine group. This finding is consistent with overall high efficacy against all Covid-19 cases."

"The severe case split provides preliminary evidence of vaccine mediated protection against severe disease, alleviating many of the theoretical concerns over vaccine-mediated disease enhancement.11"

"Although the study was designed to follow participants for safety and efficacy for 2 years after the second dose, given the high vaccine efficacy, ethical and practical barriers prevent following placebo recipients for 2 years without offering active immunization, once the vaccine is approved by regulators and recommended by public health authorities."

Comments/Questions:

1. Diagnosis of covid-19 required only one symptom and a positive NAAT test. Why was only one symptom + a positive NAAT rather than an actual clinical diagnosis based upon symptoms, signs, and supportive laboratory data?

2. NAAT have proven unreliable leaving only one symptom as the basis to diagnose covid-19. Are there any other studies of experimental gene therapy that are

dependent upon a single symptom to diagnose a disease? How can this be adequate?

3. What NAAT was used and what are the statistics for false negatives and positives? Was the same test used throughout the study?

4. Aspiration was not reported as the technique for injection of the BNT162b2.

5. “All the trial data”, reported to have been available to all the authors, is no longer available with the full text of the article at NEJM.org as reported in the text. Why not?

6. Participants received “informed consent”. Where can the consent documenting risks, benefits and alternative be found?

7. Were participants with prior infection with SC2 included or not?

8. Where is the raw data for reactogenicity?

9. Complete reporting of symptoms, signs, laboratory and diagnostic studies is not provided.

10. Table S2 lists 14 disease categories after consolidating All Malignancies, Diabetes, and Liver Disease. The CDC identifies 21disease categories.[1]

    1. There were 18 subjects with dementia. What legal process was required for each of these individuals? How were they able to communicate their symptoms?
    2. What was the distribution of co-morbities the control versus experimental groups given that a major risk factor is clustering of co-morbities in subjects? Data presented in Table S2 provides no information about clustering of co-morbities in the study subjects. Some studies have indicated that covid-19 fatalities were associated with multiple co-morbidities average 3.8 per fatality.

3. Hypertension is a major risk factor that was not reported.
4. Coronary artery disease and arrythmia are risk factors for covid-19 and Prevalence Data was not reported.
5. The number of smokers and drug users was not given.
6. Age is a continuous variable. It is also a risk factor. Table 1 gives age data for 16-55 and >55 years. These categories are overly broad. More granular data is required.

11. "The incidence of serious adverse events was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively)." This data needs to be carefully examined. P2610 p2.

12. "Lymphadenopathy, which generally resolved within 10 days, is likely to have resulted from a robust vaccine-elicited immune response." Given that lymphocytopenia is associated with BNT162b2, are there other explanations for lymphadenopathy? Was splenomegaly found in these cases? What were the lymphocyte counts for study subjects?

13. "...the occurrence of adverse events more than 2 to 3.5 months after the second dose and more comprehensive information on the duration of protection remain (sic) to be determined." Shouldn't a longer follow-up period be required given the experimental nature of this gene therapy?

14. Physicians look to the NEJM as a trusted source for guiding their recommendations to patients. This publication is quite superficial given the gravity of the pandemic and the implications of administering this drug to a significant portion of the human race.

15. The medical files of all covid-19 patients should be carefully reviewed as well as random sampling of the study population.

Appendix 1:

Test and CI for Two Proportions Any Event Sample 1 Vax Sample 2 Placebo

Sample X N Sample p

1 5770 21621 0.266870

2 2638 21631 0.121955

Difference = p (1) – p (2)

Estimate for difference: 0.144916

95% CI for difference: (0.137582, 0.152249)

Test for difference = 0 (vs not = 0): Z = 38.73 P-Value = 0.000

Test and CI for Two Proportions Related Events Sample 1 Vax Sample 2 Placebo

Sample X N Sample p

1 4484 21621 0.207391

2 1095 21631 0.050622

Difference = p (1) – p (2)

Estimate for difference: 0.156769

95% CI for difference: (0.150626, 0.162913)

Test for difference = 0 (vs not = 0): Z = 50.02 P-Value = 0.000

Test and CI for Two Proportions Severe Events Sample 1 Vax Sample 2 Placebo

Sample X N Sample p

1 240 21621 0.011100

2 139 21631 0.006426

Difference = p (1) – p (2)

Estimate for difference: 0.00467436

95% CI for difference: (0.00291817, 0.00643054)

Test for difference = 0 (vs not = 0): Z = 5.22 P-Value = 0.000

Test and CI for Two Proportions Any Serious AE Sample 1 Vax Sample 2 Placebo

Sample X N Sample p

1 126 21621 0.005828

2 111 21631 0.005132

Difference = p (1) – p (2)

Estimate for difference: 0.000696143

95% CI for difference: (-0.000695265, 0.00208755)

Appendix 2:

	Pfizer Co-Morbidities		**CDC Co-Morbidities**
1	AIDS/HIV	1	Cancer
2	Any Malignancy	2	Chronic Kidney Disease
3	Cerebrovascular Disease	3	Chronic Liver Disease
4	Chronic Pulmonary Disease	4	Chronic Lung Disease
5	Congestive Heart Failure	5	Cystic Fibrosis

6	Dementia Report	6	Dementia
7	Diabetes With Chronic Complication	7	Diabetes
	Diabetes Without Chronic Complication	8	Disabilities
8	Hemiplegia or Paraplegia	9	Heart Conditions
	Leukemia	10	HIV/AIDS
	Lymphoma	11	Immunocompromised
	Metastatic Solid Tumor	12	Mental Health
9	Mild Liver Disease	13	Obesity
	Moderate or Severe Liver Disease	14	Inactivity
10	Myocardial Infarction	14	Pregnancy
11	Peptic Ulcer Disease	16	Sickle Cell Disease
12	Peripheral Vascular Disease	17	Smoking
13	Renal Disease	18	Solid organ/Stem Cell Transplant
14	Rheumatic Disease	19	Stroke or CVA
		20	Substance Use
		21	Tuberculosis

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PREVIOUS STORY

Report 22: Effects of N1-Methyl-Pseudouridine in the Pfizer mRNA Vaccine

(https://dailyclout.io/report-effects-of-n1-methyl-pseudouridine-in-the-pfizer-mrna-vaccine/)

NEXT STORY

'Ultra-Maga' OK..!

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